

## CURRICULUM VITAE

### **Shishuka Malhotra, MD**

Neuro-Behavioral Clinical Research, Inc.

4825 Higbee Ave, NW, Suite 102

Canton, Ohio 44718

Phone: 330-493-1118

Email: [smalhotra@nb-cr.com](mailto:smalhotra@nb-cr.com)

### AFFILIATIONS

Neuro-Behavioral Clinical Research, Inc.

Canton, Ohio

Center Of Mind, Brain & Behavioral Medicine

Canton, Ohio

### EDUCATION

2000-2001 Fellowship: Psychology and Research

University of Cincinnati College of Medicine, Cincinnati, Ohio

1999-2000 Chief Resident: Psychiatry

Cleveland Clinic Foundation, Cleveland, Ohio

1998-1999 Residency: Psychiatry

Cleveland Clinic Foundation, Cleveland, Ohio

1993-1994 Rotating Internship-Internal Medicine, Surgery, Psychiatry,

Ophthalmology and Radiology

Pt. Jawaher Lal Nehru Memorial Medical College, Indore, India

1993 M.B.B.S.

Mahatma Grandhi Medical College, Indore India

## PRINCIPAL CLINICAL and HOSPITAL SERVICE RESPONSIBILITIES

- 2001–2002 University Hospital – Attending Psychiatrist  
Involved in outpatient, diagnosis, medical management and consultation for patients with severe bipolar, schizoaffective disorder and mood and anxiety disorder as part of Stanley Foundation Bipolar Treatment Program affiliated with NIMH.
- 2001–2002 UC Physicians Weight Management Clinic – Medical Director  
Involved in diagnosis and medical management (psychopharmacological and therapeutic) of patients with obesity associated with mood disorders, anxiety disorders, eating disorders and other chronic medical disorders such as: diabetes, hypertension and heart diseases at weight management clinic.
- 2001–2002 University of Cincinnati – College of Medicine  
Fellowship: Psychopharmacology Research – Biological Psychiatry  
Division  
Involved in administering psychiatric rating scales, completed training in protection of human research subjects, Data analysis, biostatics, research protocol preparation and implementation, advertising, IRB approval and medical management of research patients involved in scientific meetings, peer review, resident teaching and lectures for research seminars.
- 1999 Cleveland Clinic – Chief Resident, Psychiatry  
Administrative and Clinical responsibilities as chief resident in inpatient, outpatient, Consultation–Liaison–chronic pain, Substance Abuse, Deter, ER and ambulatory settings. Experience as Administrative leader, facilitating liaison amongst different medical specialties, conducting journal clubs, case–conference, Grand Round, and research supervision. Experience in running an inpatient unit as team leader. Actively involved in medical student and resident tutorial supervision and resident recruitment.

1998 Cleveland Clinic – Resident, Psychiatry  
Involved with management and care of diverse population in all aspects of diagnostic and therapeutic psychiatry in both tertiary care hospital and community mental health settings with inpatient and ambulatory patients in departments of Consultation & Liaison, Child & Adolescent and Adult, Geriatric, Addictive Disorder, Chronic Pain, Eating Disorder, Forensic and Emergency Psychiatry.

### **ACADEMIC APPOINTMENTS**

2001–2002 Assistant Professor of Clinical Psychiatry  
University of Cincinnati College of Medicine – Cincinnati, Ohio

### **HOSPITAL APPOINTMENTS**

2001–2002 Attending Psychiatrist  
University of Cincinnati College of Medicine – Cincinnati, Ohio

2001–2001 Medical Director  
UC Physicians Weight Management Clinic – Cincinnati, Ohio

### **CERTIFICATIONS**

–2013 Certified by the Board of American Psychiatry and Neurology

\*Board eligible for Child and Adolescent Psychiatry

### **EMPLOYMENT HISTORY**

2004–Present Neuro–Behavioral Clinical Research, Inc. – President & Medical Director

4825 Higbee Ave, NW, Suite 102, Canton, OH 44718

2003–2008 S. Malhotra, MD., S. Zaidi, MD., and Counselors, Inc. – General Psychiatry

2600 Tuscarawas St. West, Suite 120, Canton, OH 44708

2002–2003 Clinical Research Limited – Director of Psychiatric Clinical Research

4565 Dressler Rd, NW, Canton, OH 44718

## TEACHING EXPERIENCE

2002–2002 University Hospital

- Advance Psychopharmacology lectures for R–3 and R–4 Psychiatry Residents
- Lecturer in Neuroscience and Brain and Behavioral curriculum for medical students.
- Outpatient supervision of medical students (Year III)
- Psychopharmacology supervision of University Hospital R–3 and R–4 psychiatry residents.

1998–1999 Cleveland Clinic Foundation

- Organization of didactics and board preparation lectures for psychiatry residents as chief residents.
- Organization, teaching and supervision of case conferences for psychiatry residents.
- Supervision and teaching medical students (inpatients and outpatients)

## PUBLICATIONS

- 2009 Long-term safety of divalproex sodium extended-release in children and adolescents with bipolar I disorder. Laura Redden, MD, PhD, Melissa DelBello, MD; Karen Dineen, MD, PhD; Timothy E. Wilens, MD; **Shishuka Malhotra, MD**; Patricia Wozniak, PhD; Namita V. Vigna, PhD; Nicholas Grecco IV, MS; Xenia Kovacs, BSc; Walid Abi-Saab, MD; Mario Saltarelli, MD; J. Child Adolescent Psychopharmacol; 2009; 19 (1): 83-89
- 2005 Obesity and Mood Disorders; S. McElroy, R. Kotwal; **S. Malhotra**; E. Nelson; P. Keck, Jr., C. Nemeroff Obesity & Mental Health Disorders: Practical & Theoretical Considerations: J. Clin Psychiatry. May 2004; 65 (5): 634-51, quiz 730
- 2004 Comorbidity of Bipolar Disorder: What Can the Clinician Do: R. Khotwal; **S. Malhotra**; S. McElroy. Primary Psychiatry, In Press

## PUBLICATIONS CONTINUED

- 2003 Associations between Metabolic Syndrome and Psychiatric Disorder  
**S. Malhotra**; S. McElroy.  
Primary Psychiatry. November 2003: 10 (11): 37-44
- 2003 Are Mood Disorders and Obesity Related?  
A Review for the Mental Health Professional  
**S. Malhotra**; S. McElroy, et al  
Clinical Psychiatry - Accepted.
- 2003 Citalopram BED study  
**S. Malhotra**; S. McElroy, et al  
Journal of Clinical Psychiatry. July 2003: 64 (7) 807-13
- 2003 Enigma of the heart: Deciphering the link between heart disease and depression.  
D. Kemp; **S. Malhotra**, et al

- Cleveland Clinic Journal of Medicine. September 2003: (70)  
9:745-61
- 2002 Obesity and Mood Disorder Related  
**S. Malhotra**  
Submitted to American Journal of Psychiatry
- 2002 Implications of possible relationship between obesity and mood disorder: Is there a role for psychopharmacology in the management of obesity?  
S. McElroy; **S. Malhotra**; Paul Keck; C. Nemeroff  
Manuscript submitted - Neuropsychopharmacology
- 2002 Orlistat misuse in patients with Bulimia Nervosa  
**S. Malhotra** & S. McElroy  
American Journal of Psychiatry. March 2002: 159 (2): 492-3
- 2002 Rapid psychosis and acute withdrawal after abrupt clozapine discontinuation  
**S. Malhotra**, K. Franco  
Psychosomatics. September - October 2002: 43 (5): 418-20

## PUBLICATIONS CONTINUED

- 2002 Venlafaxine treatment of binge eating disorder associated with obesity. A series of 35 patients.  
**S. Malhotra**; K.H. King; J.A. Wlege; L. Brusman-Lovins  
J Clin Psychiatry. September 2002: 63 (9): 802-6
- 2001 Medical Management of obesity associated with mental disorders  
**S. Malhotra** & S. McElroy  
Supplement - J Clin Psych-2002;63 [supple 4]:24-32
- 2002 Depression and Cardiovascular Diseases

**S. Malhotra, G. Tesar, K. Franco**

Current Psychiatric Reports. June 2002, Vol. 2 (3): 241-246

## LETTERS & COMMUNICATION

Post Stroke Depression

Kathleen Franco & **S. Malhotra, MD**

Am J Psychiatry 158:658-659, April 2001

## PRESENTATIONS

- 2001      Medical Management of obesity associated with mental disorders  
Symposia Foundation. Post Graduate Press  
Amelia Island, Florida

## PRESENTATIONS CONTINUED

- 2000      Cholinergic rebound after clozapine discontinuation  
Case presentation meeting at Annual Consultation Liaison Society  
Meeting  
Cleveland, Ohio 2000  
Poster presentation at Annual Internal Medicine Research Day  
Cleveland Clinic Foundation 2000
- 1999      Substance induced amnesic disorder

Case presentation and poster presentation at Annual Consultation  
Liaison Society Meeting  
Cleveland, Ohio 1999  
Poster presentation at Annual Internal Medicine Research Day  
Cleveland Clinic Foundation  
Cleveland, Ohio

## RESEARCH PRESENTATIONS

- 2008 Martens, B.E., Winstanley, E.L., Creech, R., McElroy, S.L., **Malhotra, S.**, and Keck, P.E. (October 2008). Placebo-controlled study of quetiapine fumarate monotherapy in bipolar spectrum disorder with moderate-to-severe hypomania or mild mania. Poster presented at the American Psychiatric Association's Institute on Psychiatric Services. Chicago, IL.
- 2007 Long-Term safety of divalproex ER in youth with mania L. Redden; M. Delbello; K. Wagner; T. Wilens; **S. Malhotra**; P. Wozniak; N. Vigna; X. Kovacs; N. Greco; W. Abi-Saab; M. Saltarelli
- 1999 Social phobia and substance abuse  
D. Muzina, D. Malone, **S. Malhotra**, C. Yang  
A 300 patient study assessing prognosis and treatment of social phobias and substance abuse. Ongoing

## RESEARCH PRESENTATIONS CONTINUED

- 1998-Present Present Neuropsychological sequelae and intervention in post coronary artery bypass graft.  
**S. Malhotra**, K. Franco, R. Naugle, D. Underwood  
Department of Psychiatry and Cardiology  
Cleveland Clinic Foundation

## MEMBERSHIPS



1997 – Present American Psychiatric Association  
1997 – Present Ohio Psychiatric Association  
1997 – Present American Medical Association  
2006 – Present America of Clinical Pharmacology  
2009 – Present OSMA

## LICENSE

State of Ohio: 35-07-9074

## HONORS & AWARDS

### USA

2001 Resident Research Award  
University of Cincinnati Medical Center

2000 Emory Psychiatry Resident Symposium  
Sponsored by Eli Lilly Pharmaceuticals

2000 Resident of the Year  
Career Directions Program  
Sponsored by Pfizer Pharmaceuticals

1999–2000 Chief Resident in Psychiatry  
Cleveland Clinic Foundation

2012 Who's who Award  
Excellence in Psychiatry and Clinical Research

## INDIA

Presidents Award (Twice) for participation in youth parliaments

National State Scholarship for medical education/training for scoring in the top 5% in premedical examination.

Honors – First Year of Medical School. In top 2% of class of 2000.

Gold Medalist (State Competition) Indian Classic Vocal Music

## TRAINED/PROFICIENT – RATING SCALES

**15 years experience:** CGI; PANSS; MADRS; YMRS; CDSS; BPRS; HAM-D; HAM-A; IDS; Covi-Anxiety Scale; SADS; SCID; MINI; MMSE; RUD-Lite ADAS-Cog; ADCS-ADL; ADCS-CGIC; DAD; CDR-SB; NPI; Cornell Scale for Depression in Dementia. NOSIE; Daily Life Charting; H-R QLA; EQ-6D Proxy; SQLS-R4; QoI-AD; SANS; SAPS; I Y-BOCS; Cog-State; MATRICS (MCCB); BACS; Stroop Color and Word Test; RAVLT; IntegNeuro; VAB-II, DSST; AIMS; SAS; Barnes; WMS-R; WASI; WISC-R; SB-4;  
C-SSRS (experience rating, since 2008)

## CLINICAL TRIALS

## Depression

A double-blind, efficacy and safety study of XX versus placebo-controlled, fixed dose study comparing the efficacy and safety of 2 doses (10 and 15mg) of XX in acute treatment of adults with Major Depressive Disorder.

A Phase IV, multicenter, randomized, 8-week, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy of 2 fixed doses (50 and 100 mg/day) of XX sustained-release formulation (DVS SR) in adult outpatients with Major Depressive Disorder.

A randomized, placebo-controlled, double-blind study of XX fixed-dose 12 mg and 18 mg once daily as adjunctive treatment for patients with Major Depressive Disorder who are partial responders to selective Serotonin Reuptake Inhibitor Treatment.

An 8-week, randomized, double-blind, placebo-controlled, parallel-group, multi-center study of the efficacy and safety of XX 0.5 mg and 1 mg sublingual tablets administered once daily in patients with Major Depressive Disorder (MDD).

A Phase 2, multicenter, open-label study to assess the safety and tolerability of oral XX as adjunctive therapy in the treatment of patients with Major Depressive Disorder.

A Phase 2, Multicenter, randomized, double blind, placebo controlled study of the safety and efficacy of XX as adjunctive therapy in the treatment of patients with Major Depressive Disorder.

A long-term, open-label extension study of XX in adult patients with Major Depressive Disorder.

A double-blind, placebo-controlled, fixed dose study of XX in adult patients with Major Depressive Disorder.

Randomized, double-blind, parallel-group, placebo-controlled, XX-referenced, fixed dose study comparing the efficacy and safety of XX in acute treatment of Major Depressive Disorder in elderly patients.

## CLINICAL TRIALS

### **Depression Continued:**

A multicenter, randomized, double-blind, parallel group, placebo-controlled, Phase III, long-term safety and tolerability study of XX as an adjunct to an antidepressant in patients with Major Depressive Disorder who exhibit an inadequate response to antidepressant therapy.

A double-blind, fixed-dose study of XX in adult patients with Major Depressive Disorder.

A long-term, open-label extension study of XX in adults with Major Depressive Disorder.

An 8-week, multicenter, randomized, double-blind, placebo and XX controlled study of the efficacy, safety and tolerability of XX 25 and 50 mg given once daily in the treatment of Major Depressive Disorder (MDD) following a 52-week open-label treatment with XX 25 or 50 mg.

A double-blind, multicenter, placebo and active controlled, acute and extension study of XX in the treatment of patients with Major Depressive Disorder with Melancholic Features.

A double-blind, placebo and XX controlled multicenter, dose ranging study, evaluating the efficacy and safety of XX in outpatients with Major Depressive Disorder.

A double-blind, placebo-controlled study of XX as adjunctive therapy in Major Depressive Disorder.

An eight week, double-blind, placebo-controlled, multicenter study to evaluate the safety and efficacy of 2 doses of XX and XX in Subjects with Major Depressive Disorder.

A 52-week double-blind, randomized, withdrawal, parallel-group, placebo-controlled, Phase III study of the efficacy and safety of XX as monotherapy in the maintenance treatment of patients with Major Depressive Disorder.

A six month, multicenter, randomized, double-blind, pilot study to investigate the tolerability and efficacy of XX SR compared to placebo for the treatment of mild depressive symptoms and obesity.

The study of XX and XX in combination for treatment-resistant

## CLINICAL TRIALS

### Bipolar

A double-blind, placebo-controlled evaluation of the study and efficacy of XX in patients with Bipolar Depression.

Efficacy and safety of 3-week dose XX treatment in pediatric acute manic or mixed episodes associated with Bipolar Disorder.

A 26-week open label, flexible dose trial of XX extension treatment to XX in pediatric acute manic or mixed episodes associated with Bipolar Disorder.

Study to assess the efficacy and safety of XX and XX combination versus placebo in patients ages 10–17 in the treatment of major depressive episodes associated with Bipolar I Disorder.

A double-blind, placebo-controlled, parallel-group, fixed-dosage study to evaluate the efficacy and safety of XX treatment (150 and 200 mg/day) as adjunctive therapy in adults with major depression associated with Bipolar I Disorder.

Pilot Evaluation of XX in Bipolar Illness.

An open-label study of adjunctive XX in adults with Bipolar Disorder and Acute manic depressed or cycling symptoms of unacceptable side effects.

XX in Unipolar Depression and Bipolar Disorder.

XX in the treatment of bipolar depression inadequately responsive to current therapy. A placebo-controlled investigation.

Open-label study to evaluate the safety of XX in the treatment of mania associated with Bipolar I Disorder in children and adolescents.

## **Stanley Foundation**

The Stanley foundation Bipolar Network Clinical Trial Assessment Protocol (CTA)

### **Alcohol Dependence**

A phase 2 study of XX compared with placebo for the treatment of alcohol dependence.

## **CLINICAL TRIALS**

### **Schizophrenia**

A phase 3, multicenter, double-blind comparison of Xx and XX in patients with DSM-IV-TR schizophrenia followed by open-label treatment with XX.

A 12-week, randomized, multi-center, open-label ( 912-24mg/day), flexible dose study assessing efficacy, safety and tolerability of two switch approaches in schizophrenia patients currently receiving XX, XX or XX.

A 52-week, multicenter, open-label study to evaluate the effectiveness of XX Intramuscular depot as maintenance treatment on patients with Schizophrenia "XX OPEN-LABEL" (XX Intramuscular depot program in Schizophrenia)

XX vs. XX in the treatment of Acutely Ill patients with Schizophrenia.

Use of XX vs. XX for International Schizophrenia. The assessment of the safety, efficacy, and practicality of an algorithm including XX, XX and XX for the prevention of XX-associated with weight gain in outpatients with Schizophrenia.

### **Binge Eating**

XX in the treatment of Binge Eating: A single center, open-label flexible dose study in outpatients with Bulimia Nervosa or Binge Eating Disorder.

XX in the treatment of Binge Eating: A single center, double-blind, placebo-controlled, flexible dose study in outpatients.

A multi-center, randomized, double-blind, placebo-controlled, flexible dose study to assess the safety and efficacy of XX in the treatment of moderate to severe Binge-Eating Disorder associated with obesity.

## **Opioid Dependence**

Open-label study of the safety and tolerability of XX administered to health Care Professionals participating in an extended outpatient treatment program for Opioid Dependence.

## **CLINICAL TRIALS**

## **Opioid-Induced Constipation**

A Phase 3, multicenter, randomized double-blind, placebo-controlled, parallel-group study of oral XX for the treatment of Opioid-Induced Constipation (OIC) in subjects with chronic, non-malignant pain.

## **Attention Deficit Hyperactivity Disorder**

Maintenance of response after open-label treatment with XX in adult outpatients with Attention Deficit/Hyperactivity Disorder (ADHD): A placebo-controlled, randomized withdrawal study.

A long-term, open-label, safety study of XX in children (6 to 11 years) and adolescents (12 to 17 years) with Attention-Deficit/Hyperactivity Disorder associated with insomnia.

A double-blind, randomized, placebo-controlled, multicenter, fixed dose study to assess efficacy, safety, and tolerability of XX in adults with inattentive-predominant Attention Deficit/Hyperactivity Disorder (ADHD)

## **Down Syndrome**

A 10-week, double-blind, placebo-controlled study to evaluate the efficacy and safety of XX in the treatment of the cognitive dysfunction exhibited by children with Down Syndrome, aged 11 to 17.

A 10-week, double-blind, placebo-controlled study to evaluate the efficacy and safety of XX in the treatment of the cognitive dysfunction exhibited by children with Down Syndrome, aged 6 to 10.

## **Post-Herpetic Neuralgia**

A Phase 3 multicenter, randomized, double-blind, placebo-controlled study of the safety and efficacy of once-daily XX tablets in the treatment of patients with Post-Herpetic Neuralgia.

## **CLINICAL STUDIES**

## **Alzheimer's Disease**

A Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group, efficacy and safety trial of XX in patients with Mild to Moderate Alzheimer's Disease who are APOLIP0Protein E€4 Carriers.

A Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group, efficacy and safety trial of XX in patients with Mild to Moderate Alzheimer's Disease who are APOLIP0Protein E€4 Non-Carriers.

## **Fibromyalgia**

“Effect of XX 30/60 mg once daily versus placebo in adolescents with Juvenile Primary Fibromyalgia Syndrome”.

A multicenter, multiple dose, double-blind, randomized, placebo-controlled, parallel group study of the safety and efficacy of XX in female patients with Fibromyalgia syndrome.



## **Dyslipidemia**

A randomized, double-blind, placebo-controlled, parallel group, fixed dose, multicenter, study of weight reducing effect and safety of XX in obese patients with untreated Dyslipidemia.

## **Pathological Gambling**

Use of XX in the treatment of Pathological Gambling: A randomized, double-blind study, placebo controlled and flexible dose study.

A randomized double-blind placebo controlled study to assess the efficacy and safety of XX in the treatment of pathological gambling.

## **CLINICAL TRIALS**

## **Smoking Cessation**

A twelve-week, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study with follow-up evaluating the safety and efficacy of XX for Smoking Cessation in Healthy Adolescent Smokers.

## **Co-Sub Investigator**

Co-Sub Investigator in several trials at Biological Psychiatry Division at University of Cincinnati.